HIMA
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

June 14, 1999

via **COURIER**

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Response to HIMA's Request for Extension of Comment Period for FDA Docket No. 99N-0035, Proposed Rule, Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II

Dear Sir or Madam:

The Health Industry Manufacturers Association ("HIMA") appreciates the agency's response to HIMA's request for a 90-day extension of the comment period for six[1] of the thirty eight devices for which the Food and Drug Administration proposed reclassification from Class III to Class II on March 15, 1999. HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems.

As we understand the recent response letter from Linda S. Kahan received by HIMA on June 3, 1999 by facsimile (see attached), and as clarified by subsequent conversations with agency personnel, FDA has agreed to provide an extension of time to comment on the proposed rule to reclassify these six devices, including an opportunity to comment on the special control guidance documents which are codified in the proposed regulation. FDA will proceed with the existing rulemaking for reclassification of 32 preamendments Class III devices. For the six additional devices delineated in footnote 1 to this letter, FDA will

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[1] 21 C.F.R. § 870.3450 -- Vascular graft prosthesis of less than 6 millimeters diameter; 21 C.F.R.§ 870.3620 -- Pacemaker lead adaptor; 21 C.F.R. § 870.3800 -- Annuloplasty ring; 21 C.F.R. § 870.4230 -- Cardiopulmonary bypass defoamer; 21 C.F.R. § 870.4260 -- Cardiopulmonary bypass arterial line blood filter; 21 C.F.R. § 870.4350 -- Cardiopulmonary bypass oxygenator.

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announce the availability of the guidance document/special controls upon which these reclassifications are based as soon as possible and will invite comment on these guidances for a 90-day period after the guidance documents/special controls are made available. At the same time that the agency invites comment on the guidance documents/special controls, FDA will reopen the comment period on the proposed rule to reclassify these six devices and will invite comment on the proposed rule for these six devices (which includes these guidance documents as special controls). HIMA, therefore, reserves its right to comment on both the proposed rule to reclassify these six devices, and the guidance documents/special controls for these devices.

If HIMA's understanding is incorrect, please let us know. We thank you for your prompt response to our request and for this opportunity to comment on the proposed rule.

Sincerely,

Marlene K. Tandy, scc

Marlene K. Tandy, M.D., J.D.
Director, Technology and Regulatory
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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and Associate General Counsel
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Dear Dr. Tandy,

This is in response to your request for a 90 day extension of the comment period for six[1] of the thirty-eight devices for which the Food and Drug Administration (FDA) proposed reclassification from class III into class II on March 15, 1999. FDA is providing alternative relief as described below.

You requested an extension of the comment period for these devices because FDA had not yet made available for comment the guidance documents which FDA proposed to be special controls for these devices. You requested an extension of the comment period until 90 days after FDA made the guidance documents available for public comment.

FDA agrees that there should be an opportunity to comment on a guidance document before a reclassification is finalized establishing the guidance document as a special control. In lieu of the extension you requested, FDA intends to do the following:

[1]21 C.F.R 870.3450 - Vascular graft prosthesis of less than 6 millimeters diameter; 21 C.F.R. 870.3620 - Pacemaker lead adaptor; 21 C.F.R. 870.3800 - Annuloplasty ring; 21 C.F.R. 870.4230 - Cardiopulmonary bypass defoamer; 21 C.F.R. 870.4260 - Cardiopulmonary bypass arterial line blood filter; 21 C.F.R. 870.4350 - Cardiopulmonary bypass oxygenator.

1. As soon as possible, FDA will announce in the FEDERAL REGISTER the availability for review and comment of the guidance documents for the six devices identified in your request.

2. At the same time, FDA will reopen the comment period on the proposed reclassification of these six device to run concurrently with the comment period on the guidance documents.

3. After the concurrent comment periods, FDA will incorporate any comments, if appropriate, and will finalize the reclassification of the six devices, unless comments convince FDA otherwise.

In the interim, FDA intends to move forward with the reclassification of the other thirty-two devices in the proposed rule, unless comments convince FDA otherwise.

If you have any questions about this response, please contact Joseph M. Sheehan at 301-827-2974.

Sincerely yours,

Linda S. Kahan
Deputy Director for Policy
Center for Devices
and Radiological Health